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BY E-FILE AND HAND DELIVERY

The Honorable Colm F. Connolly
United States District Court of Delaware
844 North King Street
Wilmington, DE 19801

REDACTED - PUBLIC VERSION

Re: *Genentech, Inc. v. Amgen Inc.*, C.A. No.: 17-1407-CFC (Consolidated)

Amgen respectfully asks the Court to grant the relief requested below.

I. Motion to Compel Date for Production of Unredacted Pfizer Bevacizumab Biosimilar License Agreement and Related Negotiations. About three weeks ago, Genentech and Pfizer settled a litigation that accused Pfizer's bevacizumab biosimilar product of infringing, among other things, the same patents asserted against Amgen here, entering a license that is responsive to Amgen's longstanding discovery requests. As a result, the agreement—the *only* Genentech license to a bevacizumab biosimilar—and associated negotiations are relevant to damages and Genentech's claim for injunctive relief in this case. *See, e.g., ResQNet.com, Inc. v. Lansa, Inc.*, 594 F.3d 860, 872 (Fed. Cir. 2010) (for determination of damages, "the most reliable license in this record" was a settlement agreement, and the "district court may also consider the panoply of 'events and facts that occurred [after the hypothetical negotiation] and that could not have been known to or predicted by the hypothesized negotiators.'").[1] The communications, for example, could provide evidence of factors the parties would have considered in a hypothetical negotiation to determine the reasonable royalty under 35 U.S.C. § 284, and rebut Genentech's irreparable harm arguments. *Id.*; *see also High Tech Med. Instrumentation, Inc. v. New Image Indus., Inc.*, 49 F.3d 1551, 1556 (Fed. Cir. 1995) (Evidence of an offered license "suggests that any injury suffered [] would be compensable in damages assessed as part of the final judgment in the case."); Ex. 1, Req. 75-76 at 1-2 (Genentech requesting Amgen's communications regarding licensing). Genentech and Pfizer have imposed unreasonable conditions for the production.

First, Genentech and Pfizer are delaying production of the documents. They have not agreed to produce communications regarding the license or even identify a date certain by which the agreement itself will be provided. Ex. 2, ¶1 at 2-1. With fact discovery closed and expert discovery looming, Amgen cannot continue to wait indefinitely. Amgen respectfully requests that the Court compel production within one week of its order on this motion.

Second, Genentech and Pfizer stated that they intend to redact ex-US information from the documents—a condition the Court should reject. *Id.* Genentech has conceded the relevance of

[1] *See also Tyco Healthcare Grp. LP v. E-Z-EM, Inc.*, 2010 WL 774878, at *2 (E.D. Tex. Mar. 2, 2010) ("in light of the admissibility and importance of prior related settlement agreements, *ResQNet* suggests that the underlying negotiations are relevant to the calculation of a reasonable royalty using the hypothetical negotiation damages model."); *cf. In re MSTG, Inc.*, 675 F.3d 1337, 1348 (Fed. Cir. 2012) (affirming order compelling production of settlement negotiations).

the ex-US information by moving (successfully) to compel certain ex-US financial information from Amgen. *See* Ex. 3 (Mar. 12, 2019 Hr'g 62:12-63:20) at 3-3. Moreover, shielding the ex-US information from the license will prevent Amgen from understanding the full consideration exchanged between the parties.

Third, Genentech and Pfizer improperly seek to re-litigate that license agreements should be produced on an outside counsel only basis in contravention of the Court's May 16 and 29, 2019 orders (D.I. 387) compelling production of the Genentech/Pfizer Herceptin agreement under the terms of the Protective Order. Not only is this inconsistent with the Court's orders, but it is also inconsistent with Pfizer's action of publicly announcing the launch date of its bevacizumab biosimilar[2]. The Court should require production under the existing Protective Order (D.I. 206).

II. Motion to Compel Unredacted Versions of Genentech's Herceptin Litigation License Agreements. Similarly, Genentech has refused to produce unredacted versions of the Herceptin litigation settlement agreements. At the May 16, 2019 hearing and in the associated order (D.I. 387), the Court granted Amgen's motion to compel Genentech's license agreements from the Herceptin litigations, making clear that "[w]hile Genentech may redact the agreed-upon launch dates and confidential terms that are not relevant to the consideration for the licenses, Genentech may not redact any other terms of the licensing and/or settlement agreements that have any relevance to the value placed upon any of the patents implicated therein, including . . . any other consideration identified in the agreements." D.I. 387, at 2. Genentech, in response, produced redacted versions shielding nearly every term related to consideration. *See* Ex. 4, at, e.g., 4-68 through 4-70 (identifying only [redacted], but redacting other terms, including staggered launch timing, which may bear on the value placed on the license); Ex. 5, at 5-56 through 5-59 (same); Ex. 6, at 6-7 through 6-9 (same).[3] Despite the Court's caution to Genentech about the consequences of its redactions (Ex. 8 (May 16, 2019 Hr'g 49:9-23) at 8-3, Genentech continues to prejudice Amgen by withholding discoverable information (including launch timing) that is now relevant to damages and the availability of injunctive relief, including Genentech's claim for a permanent injunction based on the asserted patents. The Court should compel production of unredacted versions of Genentech's Herceptin license agreements.

III. Re-Production of 30(b)(6) Designee Regarding Genentech's [redacted] The antibody A4.6.1 was used to make the humanized antibody bevacizumab at issue in three asserted patents (the "Baca Patents"). Before the Baca Patents' priority date, [redacted]. Amgen sought discovery to test

[2] https://www.centerforbiosimilars.com/news/pfizer-confirms-it-plans-to-launch-bevacizumab-biosimilar-on-december-31

[3] The most recently-produced license, [redacted], is more properly redacted in line with D.I. 387, but still withholds ex-US consideration terms. Ex. 7, at 7-58, 7-60, 7-62 (identifying US launch date and staggered launch consideration terms but redacting ex-US consideration provisions).

that claim, including documents and testimony, because the public availability of A4.6.1 is relevant to Amgen's invalidity defense. Ex. 9, at 9-1; Ex. 10 at 10-3.

Despite its clear relevance, Genentech continues to impede Amgen's ability to obtain this discovery. For example, only on September 11, 2019 did Genentech first identify a relevant witness, Napoleon Ferrara, and designated him under Rule 30(b)(6). Ex. 11 at 11-2. The next day, Genentech offered a date for Dr. Ferrara's deposition less than one week later—representing that this was the only date available in September and that the witness had little availability in October, forcing Amgen to proceed with the deposition. *See* Ex. 12 at 12-1; Ex. 13 at 13-1. Without warning, the day before Dr. Ferrara's deposition in San Diego and while Amgen's counsel was in transit, Genentech produced hundreds of pages of relevant documents regarding [redacted] hindering Amgen's ability to meaningfully prepare for the deposition. Ex. 13 at 13-2. Yet, even that last minute production was deficient. At the deposition, Dr. Ferrara testified that he had reviewed documents regarding [redacted] that had not been produced. *Id.* Despite being designated as Genentech's corporate representative, the witness refused to testify regarding central aspects [redacted]. *Id.* After the deposition, Genentech provided a supplemental interrogatory response and over 100 additional documents relevant to this issue. Genentech acknowledged during a meet and confer on October 7, 2019 that its production is still incomplete with no concrete timetable for completion. Ex. 2, ¶2 at 2-1. Amgen therefore asked Genentech to produce another witness on this subject matter, but Genentech refused. It is indisputable that this information is relevant to the validity of the Baca Patents, and that Genentech has impeded discovery. Amgen respectfully asks the Court to compel a 30(b)(6) witness on [redacted] within two weeks of its order, and a complete production of documents on this issue one week beforehand.

IV. Motion to Compel Documents Regarding Inventor Dr. Leonard Presta's Development of a Prior Art Method [redacted] Dr. Presta, a named inventor on the Baca Patents, is also a co-author of a prior art reference describing a "stepwise humanization method" that Amgen contends renders obvious the Baca Patents. Ex. 14 (Excerpt of Supp. Resp. Genentech Interrog. No. 13 dated Sept. 20, 2019), at 14-3 through 14-5. At his deposition, Dr. Presta [redacted] *E.g.*, Ex. 15 (Presta Tr. 151:16-153:11 (15-2 through 15-3), 157:11-161:20 (15-5 through 15-9), 213:8-219:9 (15-11 through 15-17). In light of Dr. Presta's testimony [redacted], Amgen requested Dr. Presta's documents [redacted]. *See id.* at 162:2-22 (15-10). These discrete documents are highly relevant to Amgen's invalidity arguments regarding the Baca Patents. Amgen, for example, should be able to discover the [redacted] Genentech refuses to produce these documents, and Amgen therefore asks the Court to compel their production within one week of its order on this motion.

Respectfully,
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